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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,624	10/13/2005	Jesper Mortensen Haaning	0267us310	4465

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MAXYGEN, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
515 GALVESTON DRIVE  
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EXAMINER
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ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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06/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,624	<b>Applicant(s)</b> HAANING ET AL.	
	<b>Examiner</b> HOPE A. ROBINSON	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,13,14,25-28,30,32,35,50,51,53-55,62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 51,53,54,62 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,13,14,25-28,30,32,35,50 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/16/06;1/3/06;2/6/07</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election without traverse of Group I (claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 47, 50 and 55, species L65Q) on March 26, 2008 is acknowledged.

### ***Claim Disposition***

2. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50, 51, 53-55 and 62-63 are pending.  
Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are under examination.  
Claims 51, 53-54 and 62-63 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.
3. The Amendments filed on have been received and March 26, 2008 and March 30, 2005 entered.

### ***Drawing***

4. The drawings filed March 30, 2005 have been accepted by the examiner.

### ***Sequence Compliance***

5. It is noted that applicant's filed a new electronic copy of the sequence listing, therefore applicants need to provide a statement indicating that electronic and paper copy of the sequence are identical and that no new matter is included to comply with the sequence rules.

Correction is required.

### ***Information Disclosure Statement***

6. The Information Disclosure Statements filed on January 3, 2006, February 6, 2007, July 2, 2007 and November 16, 2006 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

### ***Specification***

7. The specification is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TWEEN-20<sup>®</sup>, TWEEN-80<sup>®</sup>, for example, have been noted in this application (see pages 61 and 70). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that the entire specification is reviewed for others.

The specification is objected to because at page 48, the address for ATCC is disclosed as Rockville, MD and ATCC is now in Manassas, VA.

The specification is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 22 for example. It is suggested that http:// is deleted.

The specification is objected to because the priority information is missing from the first page, for example, "This application is the national stage of the PCTDK03/00632, filed September 26, 2003".

Correction is required

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite added material, which is not supported by the original disclosure. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 recite "An isolated or recombinant FVII or FVIIa" and the instant specification talks in general about what "isolated means" in association with a polypeptide or nucleic acid, however does not explicitly teach "an isolated FVII or FVIIa" (see paragraphs 0098,0256, 0305). Support was found for the term "recombinant" only. In addition, no support was found in the instant specification for the language "no more than 15 amino acid residues", because the instant specification discloses that the invention "comprises 1-15 amino acid modifications", see for example paragraphs 24 and 35. Therefore, the specification lacks adequate written description.

### ***Basis For NonStatutory Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). 1-50 and 55-56

10. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-20, 25, 31-43, 45-48 of copending Application No. 11/021,239. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

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Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending application claim is directed to a recombinant FVII or FVIIa polypeptide variant having clotting activity comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO:1 in no more than 15 amino acid residues, wherein the arginine residue in position 36 of SEQ ID NO:1 is substituted with a negatively charged amino acid residue in the variant, and wherein amino acid positions of the variant are numbered according to SEQ ID NO:1.

The two sets of claims differ as the instant claims recite "modifications selected from L39, I42, S43, K62, L65, F71, E82 and F275", however the copending application claim contemplate a modification at position 36. The two sets of claims are related as a genus and species since the copending claims would be the genus of the specific species recited in the instant application with the open language of comprising no more than 15 amino acid substitutions, thus the recited position would be encompassed and is obvious in view of the disclosure that positions 46-406 of SEQ ID NO:1 can be mutated (see paragraph 0145 of the instant application specification).



Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the copending claims to recite, for example the species that is contained in the instant application because the copending application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the copending claims are a genus over the copending species. Thus, the copending claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

11. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33 and 41-48 of copending Application No. 11/381, 713. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a FVII or FVIIa polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced in vivo N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are

directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

12. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33, 41-43 and 48 of copending Application No. 11/381, 717. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L)

in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a Factor VII (FVII) or Factor VIIa (FVIIa) polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced in vivo N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant

application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

13. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33, 41-43 and 48 of copending Application No. 11/381, 718. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to

a FVII or FVIIa polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced *in vivo* N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious

variation of the instant application claim, therefore *prima facie* obvious.

14. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33, 41-43 and 48 of copending Application No. 11/381, 705. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a Factor VII (FVII) or Factor VIIa (FVIIa) polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human

Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced in vivo N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.



15. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 20, 25, 31-41 and 57-64 of copending Application No. 11/379, 664. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a recombinant Factor VII (FVII) or Factor VIIa (FVIIa) polypeptide variant comprising the amino acid sequence shown in SEQ ID NO: 1 with six amino acid substitutions, said six amino acid substitutions consisting of a glutamic acid residue substituted for the arginine residue in position 36, a glutamine residue substituted for the proline residue in position 10, a glutamic acid residue substituted for the lysine residue in position 32, a

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glutamic acid residue substituted for the alanine residue in position 34, an asparagine residue substituted for the threonine residue in position 106, and an asparagine residue substituted for the valine residue in position 253 of SEQ ID NO:1.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues " however the copending application claims have the open language of comprising thus the recited 6 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application claim 31 is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10, 34, 106, 253 and 32", however, note that the depending claims in the instant application recites the same positions, see for example claim 14. Furthermore, the structure of SEQ ID NO:1 and SEQ ID NO:2 are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

16. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected

under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 41, 48, 64-67, 82-83, 91 and 95-96 of copending Application No. 10/512,754. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a recombinant FVII or FVIIa polypeptide variant comprising the amino acid sequence shown in SEQ ID NO:2 with four amino acid substitutions consisting of P10Q, K32E, T106N, and V253N, wherein amino acid positions of the variant are numbered according to SEQ ID NO:2.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of

comprising thus the recited 1-15 amino acid substitutions can be 20, 50, 100 or more amino acid substitutions. Moreover, the recited sugar moiety in the copending application claim 31 is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10, 34, 106, 253 and 32", however, note that the dependent claims in the instant application recites the same positions, see for example claim 14. Furthermore, the structure of SEQ ID NO:1 and SEQ ID NO:2 are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

17. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-17, 54, and 59 of copending Application No. 10/549, 506. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have

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been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a variant of FVII or FVIIa, wherein said variant comprises 1-15 amino acid modifications as compared to hFVIIa or FVIIa (SEQ ID NO:2), including at least one amino acid modification in a position selected from the group consisting of positions 196, 237 and 341.

The two sets of claims differ as the instant claims recites in some of the mutated positions, however, the instant claims would be a genus over the species recited in the copending application since the language is open with no more than 15 modifications. Furthermore, the instant disclosure contemplates the modifications in the copending application. Further, the structure of SEQ ID NO:1 and SEQ ID NO:2 are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for

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example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

### ***Conclusion***

18. No claims are presently allowable. The mutation L65Q is free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, Ph.D., can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Hope A. Robinson/

Primary Examiner, Art Unit 1652